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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,775	01/10/2002	Eric Brown	P07023US01/BAS	3155
881	7590	06/29/2004	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/041,775	Applicant(s) BROWN ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 ~~is/are~~ pending in the application.
- 4a) Of the above claim(s) 5-8, 10 and 13-15 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 11, 12 and 16 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>61702</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

- 1) Acknowledgment is made of Applicants' preliminary amendment filed 03/26/02.

Election

- 2) Acknowledgment is made of Applicants' election filed 10/22/03 in response to the restriction requirement mailed 09/23/03. Applicants have elected invention III, claims 9, 11 and 12. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Applicants have further elected the toxic shock syndrome species, with traverse, in response to the species election requirement mailed 01/13/04. Applicants' traversal is on the grounds that the two conditions are associated with overstimulation of T-cells and are not patentably distinct; and that there is no serious burden. Applicants acknowledge that the conditions arise from different stimuli. Applicants cite MPEP 803 and state that if the search and examination of an entire application can be made without serious burden, it must be examined on the merits, even if it is asserted that it includes claims to independent or distinct inventions.

Applicants' arguments have been carefully considered, but are non-persuasive. As set forth previously, the toxic shock syndrome and poison ivy are distinct in their bacterial and non-bacterial etiology. While the former requires a search in class 424, subclasses 236.1 and 237.1 the latter requires a search in class 514, subclass 862. Thus, the searches for the two species are non-coextensive. The election of species requirement is proper and is maintained.

Status of Claims

- 3) Claims 1-16 are pending.

Claims 5-8, 10, 13, 14 and 15 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Elected claims 9, 11 and 12, to the extent these claims encompass Map19, and the linking claims 1-4 and 16 are under examination. A First Action on the Merits on these claims is issued.

Sequence Listing

- 4) Acknowledgment is made of Applicants' submission of raw sequence listing and CRF which

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have been entered on 04/11/02.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' Information Disclosure Statement filed 06/17/02. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

6) The instant application claims priority to the provisional application, 60/260,523, filed 01/10/2001.

Specification

7) The specification is objected to for the following reasons:

The use of the trademarks in the instant specification has been noted in this application. For example, pages 9, 10 and/or 28: 'Qiagen'; 'Sigma'; and 'Sepharose'. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

Double Patenting

8) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal

disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of the co-pending application, SN 09/982,992. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claimed in the co-pending application is encompassed within the scope of the instant claims.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 1-4, 9, 11, 12 and 16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant(s) regards as the invention.

(a) Claim 2 is vague and indefinite in the use of an abbreviation in the claim language: 'DTH', because it is unclear what does this stand for. It is suggested that Applicants use the full terminology at first occurrence with the abbreviation retained within the parentheses.

(b) Claim 2 is incorrect and/or lacks proper antecedence in the recitation: 'An method according to Claim 1'. It is suggested that Applicants replace the recitation with --The method according to claim 1--.

(c) Claim 3 is indefinite and are inconsistent in the recitations: 'pathogenic conditions associated with overstimulation of T cells' (see lines 1 and 2) and 'a condition associated with overstimulation of T cells' (see line 4). It is unclear whether or not these two conditions are one and the same, or how they differ from each other.

(d) Analogous criticism applies to claim 11.

(e) Claim 4 lacks proper antecedence in the recitation: 'A method according to Claim 3'. It is suggested that Applicants replace the recitation with --The method according to claim 3--.

(f) Claim 9 improperly depends from a non-elected claim.

(g) Claim 1 appears to lack proper antecedence in the recitation: 'a T cell-mediated response in the host' (see line 3), because line 1 of the claim already recites 'a T cell-mediated

response in a host'. If the two recitations are referring to the same T cell-mediated response, it is suggested that Applicants replace the recitation in line 3 4 with --said T cell-mediated response--.

(h) Claim 9 appears to lack proper antecedence in the recitation: 'a T cell-mediated response in the host' (see lines 3 and 4), because line 1 of the claim already recites 'a T cell-mediated response in a host'. If the two recitations are referring to the same T cell-mediated response, it is suggested that Applicants replace the recitation in lines 3 and 4 with --said T cell-mediated response --.

(i) Analogous criticism applies to claim 16.

(j) Claim 12 lacks proper antecedence in the recitation: 'A method according to Claim 11'. It is suggested that Applicants replace the recitation with --The method according to claim 11 --.

(k) Claim 12 has improper antecedence in the limitation: 'the pathogenic condition associated with' (see line 1). Claim 12 depends from claim 11, which recites 'a condition associated with'.

(l) Claim 16 is incorrect in the redundant recitation 'the the' (see line 2).

(m) Claims 1, 3, 11 and 16 are vague in the limitation: 'Map' or 'Map19' because these terms fail to specifically and unambiguously set forth the metes and bounds of the protein in the claimed and methods such that the skilled artisan would be readily appraised of that which is claimed.

(n) Claims 2-4, 9 and 12, which depend directly or indirectly from claim 1 or claim 11, are also rejected as being indefinite, because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12) Claims 1-4, 9, 11, 12 and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hook *et al.* (US 5,648,240 - Applicants' IDS) as evidenced by Kaempfer *et al.* (US 2002/0028211A1).

It is noted that the recited Map protein is not identified by its structure or SEQ ID number, or by its molecular weight. The limitations of 'Map protein' and 'Map19 protein' are viewed merely as names which do not impart any structure that distinguishes the product of the prior art from the recited product.

Hook *et al.* disclosed methods of eliciting a cellular response (i.e., modulating a T cell-mediated response) by administering an amount of *S. aureus* MHC Class II antigen (i.e., a Map protein) or a composition comprising the isolated protein, to humans or animals for inhibiting staphylococcal infections, or autoimmune diseases. Hook *et al.* taught that the Map or MHC analog protein stops the proliferation of CD4 T-helper cells. See claims 21 and 23; paragraph bridging columns 3 and 4; column 2, lines 42-51; Example 10; lines 3-8 in column 4; and last half of column 2. The protein contained in a pharmaceutically acceptable dispensing agent and/or adjuvants is taught (column 3, first full paragraph). The administration of such a protein composition to animals is to block the proliferation of CD4 T-helper cells (see Example 10). In view of the lack of structure for the recited Map protein, the MHC analog protein from *S. aureus* of Hook *et al.* in the prior art method is deemed to meet the claim limitation of 'Map protein' and 'Map19 protein'. That the toxic shock syndrome recited in claim 4 qualifies as a staphylococcal infection and therefore is encompassed in the staphylococcal infections described by Hook *et al.* is inherent from the teachings of the prior art in light of what is known in the art. For example, Kaempfer *et al.* taught toxic shock syndrome to be of staphylococcal etiology and its association with overstimulation of T cells. See section [0009].

Claims 1-4, 9, 11, 12 and 16 are anticipated by Hook *et al.*

Objection(s)

- 14)** Claims 9, 11 and 12 are objected to for including non-elected subject matter.

Remarks

- 15)** Claims 1-4, 9, 11, 12 and 16 stand rejected.
- 16)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the

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notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM facsimile center receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER